IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8976

Bartle, J. November 28, 2012

Marjorie H. Gendreau ("Ms. Gendreau" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, David H. Cooke, M.D. Based on an echocardiogram dated January 10, 2002, Dr. Cooke attested in Part II of Ms. Gendreau's Green Form that she suffered from severe aortic regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[3] Based on such findings,

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2. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Cooke also attested that claimant suffered from mild mitral regurgitation, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction of less than 30%, and New
(continued...)

claimant would be entitled to Matrix A-1, Level III benefits in the amount of $595,923.[4]

Dr. Cooke also attested in claimant's Green Form that Ms. Gendreau did not have aortic sclerosis at the time she was first diagnosed with mild or greater aortic regurgitation. Under the Settlement Agreement, the presence of aortic sclerosis in claimants who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive[5] requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). As the Trust does not contest Ms. Gendreau's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In March, 2005, the Trust forwarded the claim for review by Ioannis P. Panidis, M.D., F.A.C.C., one of its auditing cardiologists.[6] In audit, Dr. Panidis concluded that there was

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3. (...continued)
York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

5. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve...." Settlement Agreement § I.22.a.

6. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 24, 2004), all Level III, Level IV, and Level V Matrix claims are subject to (continued...)

no reasonable medical basis for Dr. Cooke's finding that claimant did not have aortic sclerosis based on claimant's January 10, 2002 echocardiogram. Specifically, Dr. Panidis stated that "[t]he aortic valve appeared trileaflet and mildly thickened with preserved excursion consistent with aortic sclerosis (patient was 67 years old at the time of the echo study)."

Based on the auditing cardiologist's finding that claimant had aortic sclerosis, the Trust issued a post-audit determination that Ms. Gendreau was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant argued that she was entitled to Matrix A benefits because the echocardiogram by which she was first diagnosed as FDA Positive, dated July 21, 1999, did not demonstrate that she had aortic sclerosis.[8] In support, she submitted a letter from Dr. Cooke

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6. (...continued)
the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1 claim, pursuant to the PPP, the Trust audited Ms. Gendreau's claim.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Gendreau's claim.

8. There is no dispute that claimant was first diagnosed as FDA
(continued...)

wherein he stated that "calcification was not present [on the July 21, 1999 echocardiogram]." Ms. Gendreau also asserted that the answers to the questions in her Green Form entitled her to Level IV benefits, but she did not identify which answers would satisfy the criteria set forth in the Settlement Agreement.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Panidis submitted a declaration in which he concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Gendreau did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. Specifically, Dr. Panidis stated that:

> I again concluded that Ms. Gendreau had aortic sclerosis. During my review, I noted the unequivocal presence of mild thickening of the aortic valve, specifically on the non-coronary cusp, on Ms. Gendreau's July 21, 1999 echocardiogram. I observed this same thickening of the non-coronary cusp in the other echocardiograms submitted by Ms. Gendreau.

The Trust then issued a final post-audit determination, again determining that Ms. Gendreau was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

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8. (...continued)
Positive after reaching the age of sixty.

show cause why Ms. Gendreau's claim should be paid. On November 8, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5841 (Nov. 8, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 8, 2006, and claimant submitted a sur-reply on March 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

reasonable medical basis for the attesting physician's finding that she did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Gendreau argues that there is a reasonable medical basis for the attesting physician's finding that she did not have aortic sclerosis at the time she was first diagnosed as FDA Positive because neither the July 21, 1999 echocardiogram report nor the May 21, 2001 echocardiogram report indicates that she suffered from aortic sclerosis. Claimant contends that if the condition was present it would have been noted on the echocardiogram report. In addition, claimant asserts that, "[i]n most cases, the first sign of aortic sclerosis ... is a heart murmur detected during a cardiac examination," and that reports from cardiac examinations conducted in July, 1999 and August, 2009 indicate that she did not suffer from a heart murmur. Ms. Gendreau further maintains that the finding of aortic sclerosis is merely a difference of opinion between "several different interpreters" and the auditing

cardiologist. Claimant also argues that the auditing cardiologist failed to provide any medical data or objective observations that claimant could "challenge or refute." Finally, she contends that there is no evidence the "mild thickening" detected by the auditing cardiologist constitutes aortic sclerosis as that term is used in the Settlement Agreement.[10, 11]

In response, the Trust argues that claimant has failed to meet her burden of proof because she does not address or rebut the auditing cardiologist's finding that claimant's July 21, 1999 echocardiogram demonstrated aortic sclerosis. In addition, the Trust asserts that claimant provided no citation to any expert testimony to support her contention that if she suffered from aortic sclerosis at the time of her July 21, 1999 echocardiogram she would have possessed a heart murmur.

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10. Ms. Gendreau also argues that her benefits should be based on an age at diagnosis of 64 rather than 67 because she was diagnosed as FDA positive by an echocardiogram of July 21, 1999. We disagree. Claimant's age at diagnosis for purposes of calculating her benefit amount is the date on which she satisfied the criteria for payment of Matrix Benefits. Here, that is the date of her valvular repair/replacement surgery. Ms. Gendreau had surgery on April 30, 2002, when she was 67 years of age.

11. In addition, Ms. Gendreau asserts she is entitled to Level IV benefits because a May 23, 2002 echocardiogram that she submitted during contest indicates her ejection fraction was less than 40% within six months after her valvular repair/replacement surgery. A Level IV claim, however, requires an ejection fraction less than 40% six months or more after surgery, not within six months after surgery. As the May 23, 2002 echocardiogram was performed less than one month after claimant's surgery, which was performed on April 30, 2002, it cannot satisfy the requirements of a Level IV claim.

The Technical Advisor, Dr. Vigilante, reviewed claimant's July 21, 1999 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. Specifically, Dr. Vigilante determined that:

> The aortic valve was significantly abnormal. There were obvious increased echoes and increased reflectance of these echoes particularly on the non-coronary leaflet consistent with calcification.... In addition, there was significant increased density of echoes and increased reflectance in the aortic annulus both in the region of the non-coronary and right coronary leaflets. All of these findings are classic for aortic sclerosis.... Significant aortic sclerosis was noted in multiple views including the parasternal long axis view, parasternal short axis view, and apical long axis view.

In addition, Dr. Vigilante reviewed claimant's May 21, 2001, January 10, 2002, and April 17, 2002 echocardiograms and observed "definite" aortic sclerosis on each of these echocardiograms.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, Ms. Gendreau does not adequately challenge the findings of the auditing cardiologist or the Technical Advisor. Specifically, Dr. Panidis observed "the unequivocal presence of mild thickening of the aortic valve, specifically on the non-coronary cusp, on Ms. Gendreau's July 21, 1999 echocardiogram." Similarly, Dr. Vigilante determined that "[t]here were obvious increased echoes and increased reflectance of these echoes particularly on

the non-coronary leaflet consistent with calcification," and that "these findings are classic for aortic sclerosis."[12] Rather than refute these findings, Ms. Gendreau relies on the reports of her July 21, 1999 and May 21, 2001 echocardiograms, which are silent on the presence or absence of aortic sclerosis, and Dr. Cooke's Green Form representation.[13] Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

In addition, there is no support for claimant's argument that "mild" thickening of the aortic valve does not constitute aortic sclerosis under the Settlement Agreement. Unlike some of the other factors that reduce a claim to Matrix B, any presence of aortic sclerosis, regardless of the amount, places the claim on Matrix B. Compare Settlement Agreement § IV.B.2.d.(2)(c)i)c) with Settlement Agreement § IV.B.2.d.(2)(c)i)d) ("Aortic root dilation > 5.0 cm").

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. Therefore,

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12. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

13. Although claimant asserted that she also would have had a heart murmur if she suffered from aortic sclerosis, she did not provide any expert submission or cite any medical literature in support of this argument.

we will affirm the Trust's denial of Ms. Gendreau's claim for Matrix A-1 benefits.